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UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. CALI RICE VALLEY, INC., a corporation, and CUONG T. DO, an individual, Defendants.	Civil No. COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), to permanently restrain and enjoin Cali Rice Valley, Inc., a corporation, and Cuong T. Do, an individual (collectively, "Defendants"), from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in the United States in a manner that fails to comply with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g;

B. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(4) or (c); and

C. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(e)(1), (f), (i)(1), (i)(2), (k) or (w).

JURISDICTION, VENUE, AND DIVISIONAL ASSIGNMENT

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391.

4. Divisional assignment to the San Francisco or Oakland Division is proper under Local Rule 3-2(c) and (d) because Cali Rice Valley has its principal place of business in Antioch and because a substantial part of the events or omissions giving rise to the claims occurred there.

DEFENDANTS

5. Defendant Cali Rice Valley, Inc., ("Cali Rice"), is a California corporation with its principal place of business at 3810 Delta Fair Boulevard, Antioch, California 94509 ("Antioch Facility"), within the jurisdiction of this Court. Cali Rice manufactures, processes, prepares, packs,

labels, holds, and distributes wheat noodles and rice noodles under the Rice Valley brand. The company has approximately 20 employees.

6. Defendant Cuong T. Do is the general manager and a co-owner of Cali Rice. Defendant Do is the most responsible person at the company, and has ultimate authority over all the company's operations, including financial expenditures, production processes, and employee supervision. Defendant Do performs his duties at 3810 Delta Fair Boulevard, Antioch, California 94509, within the jurisdiction of this Court.

7. Defendants are engaged in manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food, including ready-to-eat wheat noodles, uncooked wheat noodles, and ready-to-eat rice noodles, packaged in retail and bulk sizes, as well as bakery products, such as cakes, cookies, pastries, and breads.

8. Defendants manufacture their noodles from ingredients that originate from outside the state of California, including Thailand and Canada. Defendants distribute their noodles to customers in the Northern California Bay area.

9. Defendants' noodles are prepared in several product styles. Defendants' wheat noodles include thick-cut and thin-cut Instant Noodles that are packaged either uncooked or ready-to-eat, as well as wonton-style Instant Noodles that are packaged uncooked. Defendants' rice noodles are packaged ready-to-eat and include Hu Tieu Rice Noodle, Banh Pho Rice Noodle, Chow Fun (Thick Rice Noodle), Banh Uot Vietnamese Rice Sheet, and Banh Cuon Rice Roll. For purposes herein, Defendants' ready-to eat noodles are identified as "RTE," and their packaged uncooked noodles are identified as non-ready-to-eat ("non-RTE").

10. Defendants package their RTE and non-RTE wheat noodles in vacuum-packaging, i.e., reduced-oxygen packaging.

11. Although reduced-oxygen packaging can extend a product's shelf-life, it also may carry risks. For example, if *Clostridium botulinum* bacteria are present in packaged food such as Defendants' noodles, under certain conditions, a reduced-oxygen packaging environment may allow the bacteria to grow and form botulinum toxin, which causes botulism.

12. Although botulism is rare, all age groups are susceptible to the illness, which can be fatal even with treatment.

13. In addition, Defendants' products are at risk of contamination with other pathogens, such as *Bacillus cereus* (rice noodles) and *Listeria monocytogenes* (wheat noodles and rice noodles). The toxin produced by *Bacillus cereus* causes a vomiting syndrome, and *Listeria monocytogenes* causes listeriosis, an illness that may pose an acute, life-threatening danger in vulnerable populations.

DEFENDANTS' VIOLATIONS

Hazard Analysis and Preventive Controls

Legal Framework

14. The Federal Food, Drug, and Cosmetic Act requires that the owner, operator, or agent in charge of a food-production facility evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and to provide assurances that the food is not adulterated under 21 U.S.C. § 342 (insanitary conditions) or misbranded under 21 U.S.C. § 343(w) (allergen labeling). 21 U.S.C. § 350g (hazard analysis and risk-based preventive controls).

15. FDA promulgated the hazard analysis and risk-based preventive controls regulations ("Human Food PC Regulations") to implement 21 U.S.C. § 350g. *See* 21 U.S.C. § 350g(n); 21 C.F.R. Part 117, Subpart C. The Human Food PC Regulations are designed to protect the public health by requiring measures that provide additional assurances that food is processed in a safe and sanitary manner. *See generally* Final Rule, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls in Human Food, 80 Fed. Reg. 55,908 (Sept. 17, 2015).

16. The Federal Food, Drug, and Cosmetic Act prohibits the owner, operator, or agent in charge of a food facility ("food facility operator") from failing to comply with the requirements in 21 U.S.C. § 350g or the Human Food PC Regulations. 21 U.S.C. § 331(uu); 21 C.F.R. § 117.1(b).

17. As set forth in 21 U.S.C. § 350g and the Human Food PC Regulations, a food facility operator must prepare and implement a written food safety plan, which must contain, among other things, a written hazard analysis that meets the requirements of 21 C.F.R. § 117.130(a)(2) and written

preventive controls that meet the requirements of 21 C.F.R. § 117.135(b). *See* 21 U.S.C. § 350g(h); 21 C.F.R. §§ 117.126(a) and (b) (food safety plan).

18. Under the hazard analysis requirements, a food facility operator must "conduct a hazard analysis to identify and evaluate . . . known or reasonably foreseeable hazards . . . to determine whether there are any hazards requiring a preventive control," for each type of food manufactured, processed, packed, or held at the facility. 21 C.F.R. § 117.130(a) (hazard analysis); *see* 21 U.S.C. § 350g(b). Hazards can be biological, chemical, or physical, and include, but are not limited to, microbiological pathogens, e.g., disease-causing bacteria. *See* 21 U.S.C. § 350g(b); 21 C.F.R. § 117.130(b) (hazard identification).

19. Under the preventive controls requirements, a food facility operator must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control are significantly minimized or prevented, and that food manufactured, processed, packed, or held by the facility is not adulterated under 21 U.S.C. § 342 or misbranded under 21 U.S.C. § 343(w). 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135 (preventive controls). Preventive controls include, but are not limited to, process controls, sanitation controls, and allergen controls, as appropriate to the facility and the food. 21 C.F.R. § 117.135(c); *see* 21 U.S.C. § 350g(c).

Defendants' Violations

20. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(uu), by operating a facility that manufactures, processes, packs, or holds food for sale in the United States in a manner that does not comply with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g and the Human Food PC Regulations.

21. Defendants fail to comply with the hazard analysis and preventive controls requirements in the following ways:

A. Defendants have not conducted a hazard analysis to identify and evaluate the known or reasonably foreseeable hazards in the production of their wheat noodles to determine whether there are hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a). For example:

(1) Defendants have not identified and evaluated *Clostridium botulinum* growth and toxin formation, which is a known or reasonably foreseeable hazard in Defendants' production of RTE and non-RTE wheat noodles because Defendants package them in reduced-oxygen packaging;

(2) Defendants have not identified and evaluated the hazard of contamination with environmental pathogens such as *Listeria monocytogenes*, which is a hazard requiring a preventive control in Defendants' production of RTE wheat noodles because these noodles are exposed to the environment after cooking and before packaging where they may become contaminated with pathogens and may cause illness in consumers because they are sold as ready-to-eat and not intended to be further cooked; and

(3) Defendants have not identified and evaluated the hazard of undeclared food allergens, which is a hazard requiring a preventive control in Defendants' production of RTE and non-RTE wheat noodles because their wheat noodles contain major food allergens, e.g., wheat, eggs, which must be declared on the product label;

B. Defendants have not conducted an adequate hazard analysis to identify and evaluate the known or reasonably foreseeable hazards in the production of their rice noodles to determine whether there are hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a). For example:

(1) Defendants have not adequately evaluated the hazard of *Bacillus cereus* growth and toxin formation in their production of RTE rice noodles because Defendants' hazard analysis overlooks the fact that their product formulation along with their storage and delivery conditions can support the growth and toxin formation of *Bacillus cereus*, a bacterium commonly found in raw rice and not expected to be killed during Defendants' processing steps; and

(2) Defendants have not adequately evaluated the hazard of contamination with environmental pathogens such as *Listeria monocytogenes*, which is a hazard requiring a preventive control in Defendants' production of RTE rice noodles because these noodles are exposed to the environment after cooking and before packaging where they may become contaminated with pathogens

and may cause illness in consumers because they are sold as ready-to-eat and not intended to be further cooked; and

C. Defendants fail to have preventive controls that provide assurances that hazards requiring a preventive control are significantly minimized or prevented, as required by 21 U.S.C. § 350g(c) and 21 C.F.R. § 117.135. In Defendants' production of wheat noodles and rice noodles, the hazards requiring a preventive control include, but are not limited to, *Listeria monocytogenes* and undeclared food allergens, as described in this paragraph.

Current Good Manufacturing Practice

Legal Framework

22. Food is adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4).

23. Food manufacturers must adhere to FDA's current good manufacturing practice regulations ("CGMP Regulations"), codified at 21 C.F.R. Part 117, Subpart B, which establish basic practices that must be followed and conditions that must be maintained during food manufacturing operations. *See* 21 C.F.R. §§ 117.10 through 117.110.

24. The CGMP Regulations require, among other things, that manufacturing conditions and practices protect food, food-contact surfaces, and food-packaging materials from contamination from any source. *See generally* 21 C.F.R. Part 117, Subpart B.

25. Food may be deemed adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with 21 C.F.R. Part 117. *See* 21 C.F.R. § 117.1(a).

Defendants' Violations

26. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) because of their failure to adhere to the CGMP Regulations.

27. Defendants do not comply with the CGMP Regulations in the following ways:

A. Defendants fail to ensure that employees working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices to maintain cleanliness, as required by 21 C.F.R. § 117.10(b);

B. Defendants fail to have facilities that are designed and constructed to facilitate maintenance and sanitary operations for food production, as required by 21 C.F.R. § 117.20(b);

C. Defendants fail to conduct cleaning and sanitizing of utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 117.35(a);

D. Defendants fail to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against food contamination by pests, as required by 21 C.F.R. § 117.35(c); and

E. Defendants fail to store food under conditions that will protect against contamination and deterioration, as required by 21 C.F.R. § 117.93.

28. Based on the conditions and practices at the Antioch Facility, Defendants' food may have become contaminated with filth or may have been rendered injurious to health, thus causing their food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4).

Color Additives

Legal Framework

29. Food is adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act if it bears or contains a color additive that is unsafe within the meaning of 21 U.S.C. § 379e(a). 21 U.S.C. § 342(c). A color additive is unsafe unless its use in food conforms to the applicable regulation prescribing its conditions for use. 21 U.S.C. § 379e(a).

30. Color additives subject to certification by FDA under 21 U.S.C. § 379e(a) must be declared on the label of the food to which the coloring has been added, by the name of the color additive listed in the applicable regulation in 21 C.F.R. Parts 74 or 82. *See* 21 C.F.R. § 101.22(k)(l).

31. The color additive, FD&C Yellow No. 5, is subject to FDA certification under 21 U.S.C. § 379e(a). *See* 21 C.F.R. Part 74.

32. FDA's regulation at 21 C.F.R. § 74.705 provides the conditions for use in food of the color additive, FD&C Yellow No. 5. That regulation includes a requirement that food containing FD&C Yellow No. 5 must declare the presence of the color additive in the list of ingredients on the product label. *See* 21 C.F.R. § 74.705(d)(2).

Defendants' Violations

33. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by causing an article of food that is held for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(c) because their non-RTE wonton-style Instant Noodles contains a color additive that is not declared on the product label, as required by 21 U.S.C. § 379e(a) and 21 C.F.R. § 74.705(d)(2).

34. Defendants' non-RTE wonton-style Instant Noodles are formulated with an ingredient that contains the color additive FD&C Yellow No. 5; however FD&C Yellow No. 5 is not declared on the Instant Noodles label. As a result, this color additive is deemed unsafe within the meaning of 21 U.S.C. § 379e(a), and the Instant Noodles containing it are adulterated under 21 U.S.C. § 342(c).

Food Labeling

Legal Framework

35. Food is misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act if:

A. It is in package form and its label fails to contain the place of business of the manufacturer, packer, or distributor. *See* 21 U.S.C. § 343(e)(1) and 21 C.F.R. § 101.5(a);

B. Its label contains information in multiple languages and all required information is not in all represented languages, i.e., the English language, as well as the foreign language(s). *See* 21 U.S.C. § 343(f) and 21 C.F.R. § 101.15(c);

C. Its label fails to bear the common or usual name of the food. *See* 21 U.S.C. § 343(i)(1) and 21 C.F.R. § 101.3(b)(2);

D. It is fabricated from two or more ingredients and its label fails to bear the common or usual name of each ingredient. *See* 21 U.S.C. § 343(i)(2) and 21 C.F.R. §§ 101.4(a), (b);

E. It bears or contains an artificial flavoring, artificial coloring, or chemical preservative and its label fails to declare that fact. *See* 21 U.S.C. § 343(k) and 21 C.F.R. § 101.22(k); or

F. It contains an ingredient that bears or contains a major food allergen and its label fails to declare the major food allergen. *See* 21 U.S.C. § 343(w)(1).

Defendants' Violations

36. Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded as follows:

A. Defendants fail to label their 10-pound bags of RTE thick-cut Instant Noodles; therefore, this product is misbranded within the meaning of 21 U.S.C. §§ 343(e)(1) (place of business), 343(i)(1) (common name of food), 343(i)(2) (ingredients), and 343(w)(1) (major food allergens). Regarding 21 U.S.C. § 343(w)(1), the product contains the major food allergens, wheat and egg, but Defendants fail to have a label that declares these allergens;

B. Labels for Defendants' 16-ounce packages and 5-pound bags of Banh Uot Vietnamese Rice Sheet incorrectly list Defendants' place of business as San Francisco, California, instead of Antioch, California; therefore, the products are misbranded within the meaning of 21 U.S.C. § 343(e)(1);

C. Labels for Defendants' 14-ounce packages of non-RTE wonton-style Instant Noodles, 10-pound bags of Hu Tieu Rice Noodle, 24-ounce packages of Banh Pho Rice Noodle, 16-ounce packages of Banh Uot Vietnamese Rice Sheet, and 5-pound bags of Banh Uot Vietnamese Rice Sheet contain information in multiple languages but do not declare the ingredient statement, Nutrition Facts label, and/or net quantity of content statement in both the foreign languages and English, as required by 21 CFR 101.15(c); therefore, the products are misbranded within the meaning of 21 U.S.C. § 343(f);

D. The label for Defendants' 14-ounce packages of non-RTE wonton-style Instant Noodles does not declare its wheat starch ingredient, or the sub-ingredients of its high gluten flour ingredient, such as flour, riboflavin, ascorbic acid, and enzyme, in accordance with 21 C.F.R. § 101.4(b)(2); therefore, the product is misbranded within the meaning of 21 U.S.C. § 343(i)(2); and

E. The label for Defendants' 14-ounce packages of non-RTE wonton-style Instant Noodles does not declare that the product contains FD&C Yellow No. 5 and FD&C Yellow No. 6; therefore, the product is misbranded within the meaning of 21 U.S.C. § 343(k).

EVIDENCE OF DEFENDANTS' VIOLATIONS

FDA's Most Recent Inspection

37. FDA conducted an inspection at the Antioch Facility between November 2021–January 2022. As discussed more fully below:

A. FDA investigators documented significant deviations from the hazard analysis and preventive controls requirements and the CGMP Regulations; and

B. FDA laboratory analysis of product and environmental samples collected by FDA investigators detected: (1) product characteristics of Defendants' RTE rice noodles (Hu Tieu Rice Noodle and Banh Cuon Rice Noodle) that support the growth and toxin formation of *Bacillus cereus*; and (2) the presence in Defendants' processing areas of *Listeria innocua*, which is a non-pathogenic species that indicates that the environmental conditions support the survival and growth of the pathogen, *Listeria monocytogenes*.

Hazard Analysis and Preventive Controls Requirements

38. During the November 2021–January 2022 inspection, FDA investigators documented that Defendants have not conducted a hazard analysis to identify and evaluate the known or reasonably foreseeable hazards in the production of their wheat noodles to determine whether there are hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a). As described in paragraph 20(A):

A. Defendants have not identified and evaluated *Clostridium botulinum* growth and toxin formation, which is a known or reasonably foreseeable hazard in Defendants' production of RTE and non-RTE wheat noodles;

B. Defendants have not identified and evaluated the hazard of contamination with environmental pathogens such as *Listeria monocytogenes*, which is a hazard requiring a preventive control in Defendants' production of RTE wheat noodles; and

C. Defendants have not identified and evaluated the hazard of undeclared food allergens, which is a hazard requiring a preventive control in Defendants' production of RTE and non-RTE wheat noodles.

39. *Clostridium botulinum* is anaerobic and requires a lack of oxygen for growth and toxin formation. An FDA investigator observed that Defendants package RTE and non-RTE wheat noodles in vacuum packaging, using nitrogen gas to expel air, thereby lowering the oxygen content inside the packaged food. If *Clostridium botulinum* is present in the wheat noodles, Defendants' packaging may allow the bacteria to survive and thrive. Therefore, Defendants must evaluate the hazard of *Clostridium botulinum* growth and toxin formation in production of their wheat noodles to determine whether, based on their product formulation, processing operations, and storage conditions, a preventive control is necessary to control this hazard.

40. On January 7, 2022, Defendant Do stated to an FDA investigator that Cali Rice ceased packaging its wheat noodles in reduced-oxygen packaging as of November 2021. On January 26, 2022, Defendant Do updated his statement and told FDA investigators that the company stopped using reduced-oxygen packaging for its wheat noodles on December 10, 2021. However, after the FDA investigators checked the inventory of packaged wheat noodles in Defendants' walk-in freezer, Defendant Do again revised his statement and said that reduced-oxygen packaging was used for four lots of wheat noodles manufactured beyond the date(s) he had previously provided. Defendant Do estimated that one of those four lots was manufactured as late as January 14, 2022, which was less than two weeks since he had stated to FDA that no reduced-oxygen packaging had been used since December 10, 2021.

41. FDA investigators also documented that Defendants have not conducted an adequate hazard analysis to identify and evaluate the known or reasonably foreseeable hazards in the production of their rice noodles to determine whether there are hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a). As described in paragraph 20(B):

A. Defendants have not adequately evaluated *Bacillus cereus* growth and toxin formation, which is a known or reasonably foreseeable hazard in Defendants' production of RTE rice noodles; and

B. Defendants have not adequately evaluated the hazard of contamination with environmental pathogens such as *Listeria monocytogenes*, which is a hazard requiring a preventive control in Defendants' production of RTE rice noodles.

42. FDA investigators documented practices and conditions at the Antioch Facility that support the growth and toxin formation of *Bacillus cereus* in Defendant's RTE rice noodles, including:

A. Inadequate product formulation controls.

(1) Defendant Do stated to an FDA investigator that he increased the amount of sodium acid sulfate powder in the rice noodles to achieve a pH below 4.6, but also stated that he does not calibrate the instruments used to measure the pH;

(2) Defendants have not established written procedures for documenting the minimum amount of sodium acid sulfate powder needed for each rice noodle batch to consistently achieve a pH that is unsuitable for *Bacillus cereus* growth and toxin formation, and FDA investigators observed production employees adding different amounts of sodium acid sulfate to batches of rice noodles; and

(3) As described in paragraph 47(A)-(C), FDA laboratory analysis of Defendants' RTE Hu Tieu Rice Noodle (24-ounce package) and RTE Banh Cuon Rice Roll (16-ounce package) revealed pH and water activity parameters that are suitable for *Bacillus cereus* growth and toxin formation; and

B. Lack of time and temperature controls. Defendants' "Cali Rice Valley Food Safety Plan for Rice Noodles and Milktoast Bread," Version 1, dated June 11, 2021, requires the

temperature for "Storage and Distribution" of rice noodle to be less than 40ºF. However, Defendant Do explained to an FDA investigator that all RTE rice noodles are stored at ambient temperature and that storage at the facility before delivery is approximately 9 to 16 hours. After facility storage, Defendants' rice noodles are delivered in vans at ambient temperatures, which, according to Defendants' delivery drivers, takes approximately 6 to 9 hours to complete. Defendants have not evaluated these time and temperature practices for the hazard of *Bacillus cereus*, and they do not monitor or keep records of the time and temperature during storage and delivery.

43. FDA investigators documented inadequate sanitation controls at the Antioch Facility that present a risk of contamination of Defendants' RTE wheat noodles and RTE rice noodles with environmental pathogens such as *Listeria monocytogenes*, including the following:

A. Defendants do not conduct environmental monitoring of their wheat noodle production room or their rice noodle production room to verify that Defendants' sanitation practices are adequate to prevent the hazard of contamination with environmental pathogens;

B. Defendants' written environmental monitoring procedure, even if implemented, is inadequate because the sampling scheme for environmental swabbing is limited to an insufficient number of samples on an inadequate frequency (only six, at least once annually), and does not include the corrective actions to be taken if *Listeria monocytogenes* is detected during monitoring;

C. Defendants have not implemented their "Sanitation Program," "Sanitation Schedule Daily Records" or "Sanitation Schedule Monthly Records," dated July 23, 2021. However, even if implemented, Defendants' Sanitation Program is inadequate because it does not specify the sanitizer type and concentration to be applied; and

D. Defendants' employees dump wheat noodles into a sink basin filled with faucet water to rinse and cool them after steaming and prior to packaging, but Defendants have not evaluated this practice for the hazard of contamination with environmental pathogens.

44. FDA investigators also documented that Defendants fail to have preventive controls that provide assurances that hazards requiring a preventive control are significantly minimized or prevented, as required by 21 U.S.C. § 350g(c) and 21 C.F.R. § 117.135.

45. As described in paragraph 47(D), FDA laboratory analysis of environmental samples collected at the Antioch Facility identified the indicator species, *Listeria innocua*, in the rice noodle production room and on a wheel of a pallet jack used throughout the facility.

CGMP Regulations

46. During the November 2021–January 2022 inspection, FDA investigators documented that:

A. Defendants fail to ensure that employees working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices to maintain adequate cleanliness, as required by 21 C.F.R. § 117.10(b). For example, an investigator observed an employee handle and package RTE rice noodles and then stop to pick up plastic wrap from the floor, dispose of the plastic in a trash can, and resume handling the noodles without first changing gloves. The area of the floor where the plastic wrap was retrieved had tested positive for *Listeria innocua*. *See* paragraph 47(D) (describing subsample 45). Similarly, an investigator observed employees handle and package RTE rice noodles and then touch push carts to move products to a storage area and resume handling the noodles without first changing gloves. During sanitization of push carts, an investigator observed the cart handles touching the ground in an area that had tested positive for *Listeria innocua*. *See* paragraph 47(D) (describing subsample 42). In addition, an investigator observed employees allow their bare forearms to come into direct contact with RTE products, and not use soap and sanitizer on their forearms before handling the products;

B. Defendants fail to have facilities that are designed and constructed to facilitate maintenance and sanitary operations for food production, as required by 21 C.F.R. § 117.20(b). For example, an investigator observed drip condensate on a rice noodle line and pooling of water in the rice noodle production room. An investigator also observed pooling of water in the dry ingredient storage room, which, according to Defendant Do, was caused by rainwater leakage;

C. Defendants fail to conduct cleaning and sanitizing of utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 117.35(a). For example, an investigator observed employees use

high-pressure nozzles on hoses to spray and rinse food-contact surfaces of equipment in the rice noodle production room, although Defendants' "Sanitation Program," Version 1, dated July 23, 2021, states that "pressurized water is not used" for sanitation. In addition, an investigator determined that no sanitizer was present in the sanitizer dip compartment of a sink basin that employees use for sanitizing food-contact surfaces of equipment and utensils for handling RTE wheat noodles after steaming;

D. Defendants fail to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against food contamination, as required by 21 C.F.R. § 117.35(c). For example, an investigator observed an insect on wheat noodle dough in the wheat noodle production room. An investigator also observed doors open to the outside during production in the wheat noodle production room, leading into the rice noodle production room, and leading into the bakery production room; and

E. Defendants fail to store food under conditions that will protect against contamination and deterioration, as required by 21 C.F.R. § 117.93. For example, an investigator observed bags of ingredients stored outside and uncovered, some of which had puncture holes.

47. Defendants' unhygienic practices, inadequate operating and storage conditions, and pest-control deficiencies create an opportunity for contamination of Defendants' food with filth and/or bacteria including, but not limited to, *Listeria monocytogenes*.

Laboratory Analysis

48. During the November 2021–January 2022 inspection, FDA investigators collected samples at the Antioch Facility of Defendants' food to test pH and water activity levels, as well as environmental swabs to test for *Listeria*. FDA laboratory analyses of these samples found the following:

A. Sample 1171983—Hu Tieu Rice Noodle (24 oz.), manufactured and collected on November 4, 2021. FDA testing found a pH mean (and range) of 4.72 (4.56 to 4.85) (original test) and 4.77 (4.65 to 4.92) (check test) in subsamples 1 through 24, and water activity of 0.999 (original test) and 0.995 (check test) in subsamples 1 through 3. The pH and water activity levels in this sample of Defendants' Hu Tieu Rice Noodle can support the growth and toxin formation of *Bacillus cereus*;

B. Sample 1171984—Banh Cuon Rice Roll (16 oz.), manufactured and collected on November 5, 2021. FDA testing found a pH mean (and range) of 4.8 (4.71 to 4.87) (original test) and 4.8 (4.67 to 4.94) (check test) in subsamples 1 through 24, and water activity of 0.997 (original test) and 0.994 (check test) in subsamples 1 through 3. The pH and water activity levels in this sample of Defendants' Banh Cuon Rice Roll can support the growth and toxin formation of *Bacillus cereus*;

C. Sample 1175414—Banh Cuon Rice Roll (16 oz.), manufactured and collected on December 17, 2021. FDA testing found a pH mean (and range) of 4.7 (4.44 to 4.99) (original test) and 4.65 (4.35 to 5.06) (check test) in subsamples 1 through 24, and water activity of 0.997 (original test) and 1.00 (check test) in subsamples 1 through 3. The pH and water activity levels in this sample of Defendants' Banh Cuon Rice Roll can support the growth and toxin formation of *Bacillus cereus*; and

D. Sample 1163169—100 environmental swabs, collected on November 2, 2021. FDA testing found three swabs (identified as subsamples 42, 45, and 85) positive for *Listeria innocua*. These subsamples were taken from cracks on a wet floor in the rice noodle production room (subsample 42), a wet floor in the packaging area for RTE rice noodles (subsample 45), and a wheel of a pallet jack (subsample 85) that is used throughout the facility, in the refrigerated storage areas, the wheat-noodle production room, the rice-noodle production room, and the bakery production room.

FDA's Previous Inspections

49. Between January–April 2021, FDA conducted an inspection of Defendants' operations at their prior location, 1950 Innes Avenue, Suites 4-7 and 9-13, San Francisco, California 94124 ("San Francisco Facility"). The inspectional observations documented at the San Francisco Facility during the January–April 2021 inspection were similar to the inspectional observations made during the most recent inspection, at Defendants' Antioch Facility. During the January–April 2021 at the San Francisco Facility:

A. FDA investigators documented significant deviations from the hazard analysis and preventive controls requirements and the CGMP Regulations; and

B. FDA laboratory analysis of product and environmental samples collected by FDA investigators detected: (1) product characteristics in Defendants' RTE rice noodles (Hu Tieu Chow Fun)

that support the growth and toxin formation of *Bacillus cereus*; (2) *Listeria monocytogenes* in Defendants' processing environment; and (3) undeclared color additives in Defendants' non-RTE wonton-style Instant Noodles.

Hazard Analysis and Preventive Controls Requirements

50. During the January–April 2021 inspection, FDA investigators documented that Defendants failed to develop a written food safety plan for the food they manufactured, as required by 21 U.S.C. § 350g(h) and 21 C.F.R. § 117.126.

51. FDA investigators also documented that Defendants did not conduct a hazard analysis to identify and evaluate the known or reasonably foreseeable hazards for each type of food they manufactured to determine whether there were hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a). Specifically, the investigators observed that Defendants did not identify and evaluate the following as known or reasonably foreseeable hazards to determine whether they required a preventive control: *Clostridium botulinum* growth and toxin formation; *Bacillus cereus* growth and toxin formation; and environmental pathogens including *Listeria monocytogenes*.

52. FDA investigators documented that Defendants did not identify and evaluate *Clostridium botulinum* growth and toxin formation, which was a known or reasonably foreseeable hazard in Defendants' production of RTE and non-RTE wheat noodles because Defendants packaged them in reduced-oxygen packaging.

53. FDA investigators documented that Defendants did not identify and evaluate *Bacillus cereus* growth and toxin formation, which was a known or reasonably foreseeable hazard in Defendants' production of RTE rice noodles. An investigator observed practices and conditions that supported the growth and toxin formation of *Bacillus cereus* in Defendants' rice noodles, including:

A. Lack of product formulation controls. Defendants stated to the investigator that they did not monitor the pH of their RTE rice noodles and added undiluted sodium acid sulfate powder to drop the pH only when FDA was present. As described in paragraph 56(A), FDA laboratory analysis of Defendants' RTE rice noodles (Hu Tieu Chow Fun) revealed pH and water activity parameters that supported the growth and toxin formation of *Bacillus cereus*; and

B. Lack of time and temperature controls. An FDA investigator observed that Defendants soaked rice grains in water overnight at ambient temperatures for the next day's production of rice noodles (with a total soaking time of approximately 15.5 hours), but they had not evaluated this practice for the hazard of *Bacillus cereus*, and they did not monitor the temperature during the soaking process. An investigator also observed that Defendants stored packaged RTE rice noodles at ambient temperatures for 9 to 16.5 hours until pick-up for delivery, and then delivered the rice noodles in vans at ambient temperature, but Defendants had not evaluated these practices for the hazard of *Bacillus cereus*, and they did not monitor the temperature during storage.

54. FDA investigators documented that Defendants did not identify and evaluate the hazard of contamination with environmental pathogens, including *Listeria monocytogenes*, which was a known or reasonably foreseeable hazard in Defendants' production of RTE wheat noodles and RTE rice noodles. Investigators observed practices and conditions at the San Francisco Facility, such as inadequate sanitation controls, that presented a risk of contamination of Defendants' RTE wheat noodles and RTE rice noodles with environmental pathogens such as *Listeria monocytogenes*, including the following:

A. Defendants did not establish an environmental monitoring program and did not conduct environmental monitoring of their production areas to verify that Defendants' sanitation practices were adequate to prevent the hazard of contamination with environmental pathogens; and

B. Defendants' employees dumped wheat noodles into a sink basin filled with faucet water to rinse and cool RTE wheat noodles after steaming and prior to packaging, but Defendants had not evaluated this practice for the hazard of contamination with environmental pathogens.

55. FDA investigators also documented that Defendants failed to have preventive controls to provide assurances that hazards requiring a preventive control were significantly minimized or prevented, as required by 21 U.S.C. § 350g(c) and 21 C.F.R. § 117.135(c). The hazards requiring a preventive control included *Listeria monocytogenes*, which was detected in Defendants' San Francisco Facility, as described in paragraph 56(B)-(C).

CGMP Regulations

56. During the January–April 2021 inspection at the San Francisco Facility, FDA investigators documented that:

A. Defendants failed to ensure that employees working in direct contact with food, food-contact surfaces, and food-packaging materials conformed to hygienic practices to maintain adequate cleanliness, as required by 21 C.F.R. § 117.10(b). For example, an investigator observed employees returning directly from the break room to the rice noodle production room to package RTE rice noodles without first washing their hands;

B. Defendants failed to have facilities that are designed and constructed to facilitate maintenance and sanitary operations for food production, as required by 21 C.F.R. § 117.20(b). Specifically, an investigator observed water leaking through ceilings in Defendants' wheat and rice noodle production rooms, ingredient warehouse, and bakery production area;

C. Defendants failed to conduct cleaning and sanitizing of utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 117.35(a). For example, an investigator observed an employee using a high-pressure hose nozzle to spray the blades of the rice noodle machine, which was on a platform about 12 inches off the rice noodle production room floor. During that cleaning process, the investigator observed that the high-pressure spraying of water caused splashing from the production floor onto the machine blades (which are food-contact surfaces used to cut steamed RTE rice noodles) and onto exposed, pre-packaged, steamed RTE rice noodles that were about three feet from an area that tested positive for *Listeria monocytogenes* (*see* paragraph 56(B), describing subsample 33);

D. Defendants failed to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against food contamination, as required by 21 C.F.R. § 117.35(c). For example, an investigator observed insects, too numerous to count, flying through the wheat noodle production room during production; an insect on an uncovered container of diluted color additives during production of wheat noodles; an insect on an uncovered bun, alongside many other uncovered buns, in the bakery production area's walk-in refrigerated cooler. An investigator also observed a live bird in the wheat noodle production room on the table next to the

vacuum packaging area used for reduced oxygen packaging of retail products, and a live bird in the ambient dry ingredient storage warehouse on pallets of ingredients; and

E. Defendants failed to take all reasonable precautions throughout food manufacturing operations to ensure that production procedures did not contribute to contamination from any source, as required by 21 CFR § 117.80. For example, an investigator observed Defendants' employee submerging a hose nozzle head—that had been on the floor—into a rice solution in the mix tank to add water to the solution during production.

Laboratory Analysis

57. During the January–April 2021 inspection, FDA investigators collected samples of products to test pH, water activity levels, and color additives, as well as environmental swabs to test for *Listeria*. FDA laboratory analysis of these samples found the following:

A. Sample 1137967—RTE rice noodles (Hu Tieu Chow Fun), collected on January 27, 2021. FDA testing found a pH range of 4.97 to 5.35 (original test) and 4.99 to 5.24 (check test) in subsamples 1 through 24, and water activity exceeding 0.984 (original and check tests) in subsamples 1 through 3. The pH and water activity levels in the analyzed sample of Defendants' RTE rice noodles can support the growth and toxin formation of *Bacillus cereus*;

B. Sample 1023142—Defendants' rice noodle production room, collected on January 28, 2021. FDA testing found *Listeria monocytogenes* in subsamples 33 (swab taken from trench drain grate adjacent to equipment wheel located at north end of production line 1) and 36 (swab taken from water on floor adjacent to cart in packaging area). FDA testing also found *Listeria innocua* in subsamples 33 and 36, as well as in subsamples 34 (swab taken from floor adjacent to pallets of finished product inside perforated baskets) and 49 (swab taken from floor pit filled with water);

C. Sample 1023145—Defendants' wheat noodle production room and bakery production area, collected on February 2, 2021. FDA testing found *Listeria innocua* in subsamples 70 (swab taken from top surface of conveyor belt at beginning of noodle production line), 72 (swab taken from stagnant water over drain cover between noodle production line and retail packaging machine), 79 (swab taken from exterior surface of equipment adjacent to noodle production line), and 81 (swab taken

from exterior surface of dough mixer vat wheel). FDA testing also found *Listeria monocytogenes* and *Listeria innocua* in subsample 90 (swab taken from a pitted floor in front of three (3)-compartment sink in the bakery production area); and

D. Sample 1137968—Defendants' non-RTE wonton-style Instant Noodles, collected on January 27, 2021. FDA testing detected the presence of coloring, namely tartrazine and sunset yellow, in the product. Tartrazine is certifiable by FDA as the color additive FD&C Yellow No. 5, and sunset yellow is certifiable by FDA as the color additive FD&C Yellow No. 6. However, neither color additive is declared on the product label.

Earlier Inspections and Laboratory Analysis

58. Previously, FDA investigators conducted an inspection at the San Francisco Facility in November 2019–January 2020 and documented significant deviations from the hazard analysis and preventive controls requirements and the CGMP Regulations including, but not limited to, the following:

A. Defendants failed to have a written food safety plan, as required by 21 U.S.C. § 350g(h) and 21 C.F.R. § 117.126;

B. Defendants failed to conduct a hazard analysis to identify and evaluate the known or reasonably foreseeable hazards (including bacterial growth and toxin formation, and environmental pathogens) for each type of food manufactured at the San Francisco Facility to determine whether there are hazards requiring a preventive control, as required by 21 U.S.C. § 350g(b) and 21 C.F.R. § 117.130(a);

C. Defendants failed to have preventive controls including, but are not limited to, process controls and sanitation controls, to provide assurances that hazards requiring a preventive control are significantly minimized or prevented, as required by 21 U.S.C. § 350g(c) and 21 C.F.R. § 117.135(c);

D. Defendants failed to ensure that employees working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices to maintain cleanliness, as required by 21 C.F.R. § 117.10(b);

E. Defendants failed to have facilities that are designed and constructed to facilitate maintenance and sanitary operations for food production, as required by 21 C.F.R. § 117.20(b);

F. Defendants failed to conduct cleaning and sanitizing of utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 117.35(a); and

G. Defendants failed to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against food contamination by pests, as required by 21 C.F.R. § 117.35(c).

59. FDA also conducted an inspection at the San Francisco Facility in March–April 2019, and documented deviations from the CGMP Regulations including, but not limited to, failure to store food under conditions and controls necessary to minimize the potential growth of microorganisms and protect against contamination; failure to have facilities constructed and designed to facilitate maintenance and sanitary operations; failure to exclude pests from the facilities to protect against food contamination.

60. FDA laboratory analysis of environmental swabs collected during the November 2019–January 2020 inspection found *Listeria innocua* in Defendants' wheat noodle and rice noodle production rooms.

61. FDA laboratory analysis of samples of Defendants' wheat noodles collected during the November 2019–January 2020 and March–April 2019 inspections detected the presence of FD&C Yellow No. 5 and FD&C Yellow No. 6, but these color additives were not declared on product labels.

WARNINGS

62. On May 29, 2020, FDA issued a Warning Letter to Defendants as a result of their pervasive noncompliance documented during the November 2019–January 2020 inspection at the San Francisco Facility. The Warning Letter notified Defendants that they violated the Human Food PC Regulations, the CGMP Regulations, and various provisions of the Federal Food, Drug, and Cosmetic Act, namely 21 U.S.C. §§ 301(uu), 342(a)(4), 343, and 379e(a), which are the same violations documented during the most recent inspection, conducted at the Antioch Facility. The Warning Letter

also informed Defendants that their failure to correct their violations and prevent recurrence may result in enforcement actions, such as an injunction. Defendants did not provide a written response to the May 29, 2020, Warning Letter.

63. FDA representatives also informed Defendant Do of FDA's inspectional and laboratory findings. At the close of the inspections in November 2021–January 2022, January–April 2021, November 2019–January 2020, and March–April 2019, FDA investigators issued a Form FDA-483, List of Inspectional Observations, to Defendant Do, and discussed the inspectional observations with him.

64. During each inspection, FDA discussed its findings with the Defendants, including findings of the presence of Listeria in the Defendants' food processing facilities. During the inspection in January–April 2021, FDA representatives provided Defendant Do with the results of the FDA laboratory analysis that found Listeria, including Listeria monocytogenes, in Defendants' production area. During the inspection in November 2021–January 2022, FDA representatives provided Defendant Do with the results of the FDA laboratory analysis that found Listeria innocua in Defendants' processing areas.

65. Defendants' responses to FDA's findings are deficient in that the responses do not provide evidence that the violations have been corrected and do not include a commitment to undertake the steps necessary to bring the Defendants' food processing facility into compliance. Defendant Do's response was not adequate and did not demonstrate willingness or ability to bring Defendants into compliance with the statute.

REQUEST FOR RELIEF

66. Defendants have had ample opportunity to bring their operations into conformity with the law, but have failed to do so.

67. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Federal Food, Drug, and Cosmetic Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, cease manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food unless and until Defendants' facilities, methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food are established, operated, and administered in conformity with the Federal Food, Drug, and Cosmetic Act and its implementing regulations, in a manner acceptable to FDA;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(uu) by operating a facility that manufactures, processes, packs, or holds food for sale in the United States in a manner that fails to comply with the hazard analysis and risk-based preventive controls requirements in 21 U.S.C. § 350g; and

B. Violating 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(4) or (c), or misbranded within the meaning of 21 U.S.C. § 343.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the manufacture, processing, preparing, packing, labeling, holding, and distribution of Defendants' products to ensure continuing compliance with the terms of the injunction, and that Defendants bear the costs of such inspections at the rates prevailing at the time the inspection(s) are accomplished;

IV. Award Plaintiff costs incurred in pursuing this action, including the costs of investigation to date; and

V. Order such other and further equitable relief as this Court deems just and proper.

Dated this 11th day of October, 2022.

Respectfully submitted,

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